From: "Glover, Sherrice" <SGlover@amerisourcebergen.com>
Sent: Tue, 11 Nov 2014 10:19:55 -0500 (EST)
To: "Zimmerman, Chris" <CZimmerman@amerisourcebergen.com>
Cc: "Mays, Steve" <SMays@amerisourcebergen.com>
Subject: RE: HDMA OMP Guidelines
Attachments: DEA Chief Counsel Letter to HDMA on ICG 10-08.pdf;Final ICG on Tmplt 10-22-08.pdf

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Please see the attached.

Sherrice Glover

-----Original Message-----
From: Zimmerman, Chris
Sent: Tuesday, November 11, 2014 9:16 AM
To: Glover, Sherrice
Cc: Mays, Steve
Subject: FW: HDMA OMP Guidelines

Sherrice, I need this folder and I need you to print anything electronically kept in this matter ASAP.

Thank you,

Chris

-----Original Message-----
From: Mays, Steve
Sent: Tuesday, November 11, 2014 8:06 AM
To: Zimmerman, Chris
Subject: RE: HDMA OMP Guidelines

HDMA put together the Guidelines in October 2008 (RA09-0082) shortly after the original CAH DEA Suspension. I can't find anything on the CAH suspension but it was late 2007 or early 2008. They had another one in 2012 related to WAG.

Steve Mays
AmerisourceBergen
Senior Director, Corporate Security & Regulatory Affairs
1400 Morris Drive
Chesterbrook, PA 19087
Work: 610.727.7467
Mobile: 321.278.3292
smays@amerisourcebergen.com

-----Original Message-----
From: Zimmerman, Chris

PLAINTIFFS TRIAL EXHIBIT
P-00629

Sent: Tuesday, November 11, 2014 12:31 AM
To: Mays, Steve
Cc: Zimmerman, Chris
Subject: HDMA OMP Guidelines

Steve, do you know when HDMA published its OMP guidelines? I remember we spent some time in DC with Cardinal, McKesson, etc, and discussed the process and developed best practices that HDMA ultimately sent to DEA. Also, I am looking back to figure out when McKesson and Cardinal first underwent their DEA OMP problems.

Let me know if you know any of the above.

Thanks,

Chris

Sent from my iPad

U.S. Department of Justice
Drug Enforcement Administration

www.dea.gov

OCT 17 2008

John M. Gray
President & Chief Executive Officer
Healthcare Distribution Management Association
901 North Glebe Road
Suite 1000
Arlington, Virginia 22203

Dear Mr. Gray:

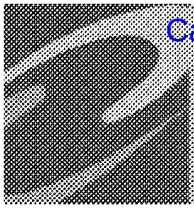
The Drug Enforcement Administration (DEA) commends the efforts of the Healthcare Distribution Management Association (HDMA) to assist its membership to fulfill their obligations under the Controlled Substances Act and implementing regulations. The elements set forth in the "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" are important to sustaining effective controls to guard against the diversion of controlled substances.

HDMA's industry compliance guidelines represent a concerted effort by HDMA and its primary distributor members to identify and articulate the responsibilities and obligations of controlled substance distributor registrants to design and operate a system to disclose and report suspicious orders as required by the Controlled Substances Act. All distributors must implement processes and procedures to effectively ensure that controlled substances are not diverted to illicit use.

Although diversion control is not a "one size fits all" effort, companies that implement processes and procedures that effectively accomplish these objectives will do much to ensure that vital controlled substances are not diverted to illegitimate uses. DEA encourages all segments of the supply chain to determine if their businesses would benefit from the development of similar, industry-specific guidelines to help support anti-diversion and compliance efforts.

Sincerely,

Wendy H. Goggin
Chief Counsel



HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA) INDUSTRY COMPLIANCE GUIDELINES: REPORTING SUSPICIOUS ORDERS AND PREVENTING DIVERSION OF CONTROLLED SUBSTANCES

Introduction

The U.S. healthcare supply chain is one of the most sophisticated in the world, providing a strong system for the safe and efficient delivery of medicines. Manufacturers, distributors, pharmacies and healthcare practitioners share a mission and responsibility to continuously monitor, protect and enhance the safety and security of this system to combat increasingly sophisticated criminals who attempt to breach the security of the legitimate supply chain.

The *HDMA Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,* have been developed as part of HDMA member distributors' ongoing commitment to the safe and efficient distribution of all prescription medicines including controlled substances. These Industry Compliance Guidelines are consistent with, and further extend, the distributors' track record of supporting and implementing initiatives designed to improve the safety, security and integrity of the medicine supply. They have been prepared in recognition of a growing problem of misuse and diversion of Controlled Substances (CS) and the critical role of each member of the supply chain in helping to enhance security.

At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers. Due diligence can provide a greater level of assurance that those who purchase CS from distributors intend to dispense them for legally acceptable purposes. Such due diligence can reduce the possibility that controlled substances within the supply chain will reach locations they are not intended to reach.

These Industry Compliance Guidelines can help identify facts and information about controlled substance product orders, and the customers placing the orders.

Healthcare Distribution Management Association (HDMA)
901 North Pitt Street, Suite 100 • Arlington, VA 22314
(703) 787-0000 • (703) 816-1120
www.HealthCareDistribution.org

History

In 1970, Congress enacted into law the Controlled Substances Act (CSA) as part of Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. The CSA provides the Drug Enforcement Administration (DEA) within the Department of Justice (DOJ) with the authority to regulate the manufacture, importation, possession and distribution of certain drugs. An additional federal agency, the Food and Drug Administration (FDA), and individual states, regulate many other aspects of drug supply chain safety and security. The CSA also created a closed system of distribution for those authorized to handle CS. Since its enactment in 1970, the CSA has been amended several times, including by the following statutes:

- The Psychotropic Substances Act of 1978;
- The Controlled Substances Penalties Amendments Act of 1984;
- The Chemical Diversion and Trafficking Act of 1988;
- The Domestic Chemical Diversion and Control Act of 1993;
- The Federal Analog Act; and
- The Methamphetamine Precursor Control Act which was superseded by the Combat Methamphetamine Epidemic Act of 2005.

The regulations in Title 21, Code of Federal Regulations (C.F.R.) part 1300 to 1316 apply to all individuals and firms desiring to conduct business in CS. All such individuals and firms must be registered with DEA, and are required to maintain complete and accurate inventories and records of all transactions involving CS, as well as security for the storage of controlled substances. Additionally, Sections 823(b) and (d) of the CSA call for the maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels.

In addition, distributors are required by 21 C.F.R. § 1301.74(b) to report suspicious orders of CS:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. [Emphasis added.]

Distribution Industry Commitment to Prevent Diversion of CS

Although distributors have been required to identify and report "suspicious orders" of CS and listed chemicals, increasing concerns about the potential misuse of prescription CS have elevated awareness within the supply chain and have led to increased expectations by DEA. Therefore, HDMA developed these Industry Compliance Guidelines to further scrutinize purchase orders for these products. For example, in public statements to Congressional Committees, DEA has noted

the growing problem of diversion and abuse of controlled pharmaceuticals, and has indicated the agency is taking stronger measures to address this matter.[1]

With the strong endorsement and expertise of our members, the Healthcare Distribution Management Association (HDMA) has developed the following Industry Compliance Guidelines for preventing diversion and reporting suspicious orders. We believe that implementation of these guidelines will help ensure that CS are appropriately distributed to supply chain customers involved in the legitimate dispensing of these important pharmaceutical products to patients, and will help distributors identify possible diversion activities.

OUTLINE

The *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substance*s, contains the following elements:

I. Know Your Customer Due Diligence
II. Monitoring for Suspicious Orders
III. Suspend/Stop an Order of Interest Shipment
IV. Investigation of Orders of Interest
V. File Suspicious Order Reports With DEA
VI. Employees, Training and Standard Operating Procedures (SOPs)
VII. Additional Recommendations
Glossary of Abbreviations

[1] See testimony provided by Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration; December 13, 2005, July 26, 2006, September 18, 2007, and June 24, 2008; and by Michele M. Leonhart, Acting Administrator, Drug Enforcement Administration, United States Department of Justice, March 12, 2008.

I. KNOW YOUR CUSTOMER DUE DILIGENCE

a. Introduction

Before opening an account for a new customer, the distributor should (i) obtain background information on the customer and the customer's business; (ii) review that information carefully, and, where appropriate, verify the information; and (iii) independently investigate the potential customer. To help ensure that the Industry Compliance Guidelines remain robust and adaptable, the "Know Your Customer Due Diligence" phase also describes "Additional Recommendations and Documentation" containing further suggestions for managing the distributor's procedures.

A distributor may tailor this part of its customer evaluation procedure to the type of customer under review. If a distributor does so, it is recommended that the distributor categorize each potential customer according to the customer's DEA "Business Activity" type as indicated on the customer's DEA registration certificate; for example, Retail Pharmacy, Hospital/Clinic, Practitioner or Distributor.

The following steps are recommended.

b. Information Gathering

All information requested by a distributor should be provided by the owner of the potential customer, the pharmacist in charge; or, in the case of a non-pharmacy customer, an equivalent designee. Each completed application, questionnaire or other document providing information requested by the distributor from the potential customer should be signed by the potential customer's owner, pharmacist in charge or equivalent designee. The signature should be notarized or should be accompanied by the statement: "*I declare under penalty of perjury that the foregoing is true and correct. Executed on [date].*"

The information gathering step would include:

- Provide potential customer with a credit application;
- Provide potential customer with a background questionnaire requesting the following information:
  - Business background,
  - Customer base,
  - Average number of prescriptions filled each day,
  - Average number of CS item prescriptions filled each day,
  - Percentage of CS purchases compared to overall purchases,
  - Verification of physical security controls for CS storage,
  - Questions based on DEA guidance and communications,
  - Copies of all their state and federal licenses and registrations,
  - If the potential customer is not currently conducting Internet prescription fulfillment, certification that they are not doing so, and will notify the distributor before conducting Internet prescription fulfillment;

- If the potential customer is conducting Internet prescription fulfillment, obtain the following information from any potential customer utilizing the Internet to receive and fill prescriptions:
    - The date the potential customer began conducting Internet prescription fulfillment,
    - Products the potential customer expects to purchase,
    - The quantity of each product the potential customer expects to purchase,
    - Practitioners who will be writing prescriptions that will be filled by the potential customer, including each practitioner's DEA and state registration and license numbers, address, telephone number(s), and other relevant contact information, and
    - National Association of Boards of Pharmacy (NABP) Verified Internet Pharmacy Practice Sites (NABP VIPPS) check.
- Names of individuals authorized to sign DEA Form 222[2],
- A description of how the pharmacy/dispenser fulfills its corresponding responsibility to ensure that the prescriptions they receive are issued for a legitimate medical purpose (as required in 21 C.F.R. § 1306.04),
- Inspections:
    - Indicate whether DEA has audited/inspected the pharmacy/dispenser over a period of at least the last two (2) years and if so, explain why,
    - Indicate whether the pharmacy/dispenser has been inspected by the state regulatory/inspection authority such as the State Board of Pharmacy, and
- Identification of physicians and other treatment centers that are the potential customer's most frequent prescribers or highest purchasing doctors.

c. Information Review

After the information is received from the potential customer, it should be reviewed thoroughly. The review should include the following steps:

- Verify that the credit application is complete, and carefully review the information submitted;
- Verify that the customer background information supplied is complete, and carefully review the information submitted;
- Verify that the answers to the questions based on DEA guidance and communications are complete, and carefully review the information contained; and
- Verify the potential customer's state and federal licenses, registrations and CS schedule authorizations.

[2] See: 21 C.F.R. § 1301 regarding *"Orders for Schedule I and II Controlled Substances"* for DEA's regulations for ordering these products by means of either DEA Form 222 or electronically, including signature requirements.

d. Independent Investigation

The distributor should independently investigate the potential customer as follows:

- Check with the distributor's local DEA office for any information regarding the potential customer, such as DEA actions against the potential customer;[3]
- Check with state oversight authorities, including the state Board of Pharmacy (for a potential pharmacy customer) and Board of Medicine (for a potential physician customer) to request further background information, such as state actions against the potential customer (some states may provide readily accessible information through the state's Web site);
- Check the DEA Web site and the Federal Register for any actions against the potential customer; and
- Conduct an Internet search, to determine whether any potential Internet business can be identified as relating to the potential customer and whether there is any other relevant information that could affect the decision to do business with the potential customer.

e. Additional Recommendations and Documentation

It is recommended that:

- Individuals selected to develop questionnaires for part (a) and to conduct reviews and investigations under parts (b) and (c) above should receive appropriate training.
- The distributor should update the questionnaire(s) periodically, particularly if a concern arises during an investigation.
- The performance and results of all steps in the customer review process should be fully documented as to each potential customer, and such documentation should be retained in an appropriate file.
- After completing the steps outlined above, the reviewer of the potential customer should sign and date the information (in a designated location of the file) to indicate that the reviewer has conducted a thorough/complete review, and that the information contained in the file is accurate and complete to the best of his/her knowledge.
- A distributor may seek further information about a potential customer, including when the distributor determines that obtaining further background information, confirmation, or verification is warranted.
- The distributor may include provisions for notification of state and federal authorities of an unlawful activity identified under the "Know Your Customer Due Diligence" as required by local, state or federal law.

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[3] Depending on the direction received from the local DEA office, the distributor may consider contacting the potential customer's local DEA office for further information regarding the potential customer.

II. MONITORING FOR SUSPICIOUS ORDERS

a. System Design

It is recommended that a distributor develop an electronic system, with accompanying written Standard Operating Procedures (SOPs), to meet the DEA's requirement in section 1301.74(b) that a distributor "design and operate a system to disclose to the registrant suspicious orders of controlled substances" (emphasis added). Distributors should assign responsibilities for identifying and investigating potentially suspicious orders, and for reporting suspicious orders. Specific elements of the monitoring system are further described below.

b. Identify Product and Customer Characteristics

Separate/classify/group customers into appropriate/different classes of trade. For example, retail pharmacies, hospitals, doctors, or dentists.

Separate the CS the distributor sells into groups or "families" of drugs (e.g., all CS items containing codeine). The following information may be useful for identifying the "families" of drugs:

- A distributor may use the DEA Web site to obtain DEA's designation of a drug's "controlled substance code number" to aid in developing a drug "family" for purposes of defining a threshold.[4]
  (See: http://www.deadiversion.usdoj.gov/schedules/schedules.htm or http://www.usdoj.gov/dea/pubs/scheduling.html)
- Distributors may also use the National Technical Information Service (NTIS) system, which (i) identifies each individual CS Stock Keeping Unit (SKU) by National Drug Code (NDC) number, (ii) lists the active ingredient and (iii) lists the corresponding DEA controlled substance code number. The DEA controlled substance code number is set up by NDC number. An electronic copy of this information may be used to help identify the drug "families."
- Alternatively, a distributor may choose to identify "families" of drugs and track the dosage unit (e.g., tablet) order levels for each SKU.[5]
- A distributor should maintain contact with DEA through the local field office or the Office of Diversion Control's Web site, www.deadiversion.usdoj.gov, to ascertain changes in diversion patterns or new "Drugs of Concern" as the information is developed by the agency. Such new information should be made part of the identification of particular CS drugs or "families" to be monitored, as appropriate.

[4] For further information on the controlled substance code numbers, see 21 C.F.R. § 1308.03.
[5] This method may present implementation challenges due to of the different strengths of the drugs.

c. Develop "Thresholds" to Identify Orders of Interest

"Thresholds" for identifying orders of interest, *i.e.*, orders that warrant follow-up inquiry to determine whether they are suspicious, may be made by using averages shipped to a particular customer facility that are consistent with the class of customers to which the particular customer belongs. It is recommended that distributors develop such thresholds by calculating the average single order and the average monthly order per "family," per customer, and class of trade.

When evaluating thresholds, orders of "unusual size" and "unusual frequency" can be used to signal that an order may need further review. Distributors are also encouraged to structure their thresholds to support evaluation of whether the order deviates substantially from a normal pattern and/or is of unusual frequency. The following examples may aid in developing the thresholds:

- Patterns of ordering such as comparing the present order to:
  - past orders from the same customer (including the frequency of orders),
  - orders for extraordinary quantities outside of normal purchasing patterns typically followed by the customer or by other customers within the same class of trade, and
  - geographical area(s) of the country they service (e.g., orders from other establishments of the same type in the locale or region),
- Orders of more than one controlled substance that are known to be taken together (combinations) outside of normal prescribing and patient treatment practices, and
- DEA/State input.

Distributors are also encouraged to consider the following when developing "thresholds":

- Quantities of products the dispenser initially indicated during the "Know Your Customer Due Diligence" phase that it expected to purchase;
- A minimum of six months sales history and a maximum of 24 months sales history are recommended; Maintain contact with DEA through the local field office or the Office of Diversion Control's Web site, www.deadiversion.usdoj.gov, to ascertain changes in diversion patterns or emerging local or regional concerns; such new information may be used to adjust thresholds as appropriate; and
- Thresholds for all new customer accounts should be established at the lowest level indicated by information obtained during the "Know Your Customer Due Diligence" review.

d. Cumulative Reviews/Thresholds

A very important component of the system will be to include a mechanism for periodic review of cumulative orders from the same customer over time, to evaluate trends in purchasing patterns. This would include, for example,

- A mechanism to compare percentages of orders for CS (individual products and/or "families") to orders of non-CS prescription drugs so as to identify a shift in a customer's business focus that may warrant further review.
- Determining if the purchaser's ordering pattern, for a period of several months, shifts in a manner inconsistent with their previous ordering patterns or inconsistent with the class of trade for that customer (e.g., a pharmacy that orders relatively few controlled substances over several months suddenly places a large order or several large orders in a concentrated period of time.)

e. Supplemental Mechanisms for Determining Orders of Interest

Distributors are encouraged to recognize that their methods for identifying an "Order of Interest" do not need to be limited to an electronic "threshold" system. Based on the distributors' knowledge of his/her customers, overall drug purchasing trends, information available from DEA and elsewhere, distributors are encouraged to allow for alternative criteria, in addition to those incorporated into the electronic system, to serve as indicators of an order of interest.

III. SUSPEND/STOP AN ORDER OF INTEREST SHIPMENT

If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.

Ideally, the electronic system would contain a process to automatically "block" the order or otherwise stop the ordered product from being shipped. The distributor may, however, ship any non-CS included in the order and any other CS products as to which the order did not exceed a threshold or otherwise become characterized as an order of interest. A distributor may choose to report an order of interest to DEA immediately as a suspicious order or may first investigate the order as described in Section IV below and report it at the conclusion of the investigation if, but only if, it is determined to be a suspicious order.

IV. INVESTIGATION OF ORDERS OF INTEREST

a. Preliminary Steps

If a product order meets or exceeds a threshold, and is thereby identified as an order of interest (or on other grounds is characterized as an order of interest), it is recommended that the distributor examine the order further. The examination is intended to aid the distributor in reaching a decision to either ship product to fill the order or to continue to hold the order. Further examination will also aid in determining whether and when to report the order to DEA under 21 C.F.R. § 1301.74(b).

The drug or drugs that cause an order to become an order of interest should not be shipped to the customer placing the order while the order is an order of interest.

It is recommended that the distributor designate a person with suitable training and experience to investigate orders of interest.

b. Initial Review

When initially reviewing an order of interest, a distributor should first examine the specific drug code product order to determine whether the reasons the order met or exceeded the thresholds, or on other grounds was characterized as an order of interest, are not "suspicious" or whether the order warrants still further examination. The examination may include obtaining additional verification from the customer that placed the order. For example, the customer may be able to identify whether the order contained an error, or whether there has been a change in the customer's business circumstances that warrants a shift in its purchasing practices that can be readily identified.

c. Investigating the Order

If, after initial review, it is determined that the order should be examined further, it is recommended that the distributor conduct an additional review as quickly as possible. The following elements are recommended as part of the additional review:

Review prior orders
The distributor should review the customer's past purchasing history for trends/discrepancies to determine whether:

- The distributor had to investigate a prior order and the circumstance and results of any prior investigation, including whether a prior order exceeded the same or a different threshold, and how the present order compares to the past order(s) of interest;
- There has been an increase (or decrease) in orders for this "group" or "family" of CS products;
- There has been other unusual activity, such as "spikes" in prior orders (e.g., a pattern of ordering over several months where the customer has placed no orders, followed by a month with a large order);

- There has been a decrease in orders for other products, (potentially indicating a shift in focus or customer base);
- There has been a change in the customer's operating environment (e.g., a new medical establishment recently opened in the customer's neighborhood);
- There has been a change in availability of drugs (such as a new drug dosage form that has recently been approved by FDA) identified as a Drug of Concern by DEA's Office of Diversion Control; and
- There are end-of-year C-II quota issues.

Interview customer

Ask: Why is there an "unusual" order? What will you do with it? Who is prescribing it? (Who, what, when, where, why, how?)

Verify customer input – (where appropriate)

How and what information provided by the customer needs to be verified will be determined on a case-by-case basis, but examples of information that could be verified include:

- If a customer says there is a new medical establishment located nearby, verify the establishment's existence, name, address, practitioner(s) names and DEA registration numbers.
- If the customer says it called DEA, verify that it actually did so.
- If the customer states that a natural disaster destroyed its pharmacy and that it must restock, verify the disaster.
- If the customer claims it "lost" a shipment, verify the loss.[6]

Additional Information

The distributor may seek additional information about the order and/or the customer who placed the order if, during the examination, it is determined that further confirmations or background information is warranted.

d. Documentation

All investigations should be fully documented, and all records of the investigation should be retained in an appropriate location within the firm (such as with other records relating to the particular customer).

At a minimum, documentation should include the name(s), titles(s) and other relevant identification of the representative of the customer contacted (e.g., "pharmacist in charge"), dates of contact, and a full description of questions asked and requests for information made by the distributor and of information provided by the customer. The documentation should include a clear statement of the final conclusion of the investigation, including why the order investigated was (or was not) determined to be "suspicious." That statement should be signed and dated by

[6] Distributors should also determine whether there is an obligation to report the loss under 21 C.F.R. § 1301.76(b).

the reviewer. Copies of any written information provided by the customer should also be retained as part of the documentation of the investigation.

e. Shipment and Reporting Decisions (under 21 C.F.R. § 1301.74(b)); SOPs

At an appropriate point in the examination process, the distributor will decide how to resolve the order, specifically, whether the order is "suspicious," and should be reported. Employees should be selected and authorized to make shipment and reporting decisions based on their knowledge of DEA requirements, the distributor's business, customers and other relevant factors. (Further recommendations as to reporting to DEA can be found in Section V below.)

Orders that are determined to be "suspicious" should be reported to DEA under § 1301.74(b) immediately upon being so determined. It is assumed that the order will continue to be placed on hold and/or cancelled, once it has been identified as "suspicious." An exception can be made if the distributor subsequently obtains additional or alternative information that leads to the conclusion that the order was misidentified as "suspicious," and/or is consistent with the pharmacy/dispenser's practice. In such instances, the order may be shipped. Full documentation of the reasons for the conclusion is recommended.

Each distributor is encouraged to develop SOPs that:

- Describe how an initial review and investigation will be conducted;
- Reflect the distributor's and its customers' business conditions;
- Are sufficiently flexible to adjust the review/investigation to address the individual product/order/customer circumstances that are likely to occur;
- Include a process and/or guidance/criteria for making the final determination that an order is, or is not, "suspicious";
- Define a process for reporting to DEA under 21 C.F.R. § 1301.74(b); and
- Define a process for allowing release of a shipment, or cancellation of an order, as appropriate.

f. Future Customer Orders

In instances where a distributor concludes that an order is (or remains) "suspicious" after conducting an investigation, in addition to notifying DEA, it is recommended that the distributor evaluate its business relationship with the customer that placed the order. The distributor may consider whether to subject future orders from the same customer for the same drug code product (or all CS) to more rigorous scrutiny than was applied before the determination that the order is suspicious. A distributor may also consider whether to cease filling all future orders of the drug code product (or all CS) placed by that customer.

V. FILE SUSPCIOUS ORDER REPORTS WITH DEA

a. Immediate DEA Notification

Under 21 C.F.R. § 1301.74(b), orders designated as "suspicious" must be reported to DEA "when discovered." Once the distributor has made the determination that an order is suspicious, a phone call to report the order to the local DEA office is recommended to meet this requirement (unless DEA provides other direction). The distributor should provide additional documentation to DEA upon request.

Additional considerations:

- Even if there is some ambiguity regarding a customer or an order's status, occasions may arise when the intended use of an order is questionable. For example, the distributor may identify information that leads them to believe that a potential customer, prior to entering a formal business arrangement with that customer, may intend to order CS products with a frequency, volume or other indicator that could be considered "suspicious." In such instances, the distributor should provide DEA with a report of this information under 21 C.F.R. § 1301.74(b).
- Distributors are strongly encouraged to regard timeliness of reporting to DEA as a critical component in meeting the requirement to report "when discovered."

b. Correspondence for Reporting

It is recommended that all correspondence to DEA (containing reports of suspicious orders) should be sent registered mail with a return receipt requested, by electronic mail or by another system that creates for the distributor a permanent record that DEA has received the notification. Although correspondence to the local DEA office is encouraged as a follow-up to a telephonic notification, distributors are encouraged to discuss with the local DEA office whether that office prefers to receive a follow-up written notice and the form for such notice.

The cover letter for reports of suspicious orders may read: "This report is submitted to you in accordance with the requirements of 21 C.F.R. § 1301.74(b) and is for (company name)." When the return receipt is received, it should be stapled to the cover letter as proof of submittal. (It is suggested that the distributor title the report "21 C.F.R. § 1301.74(b)" report.)

In some states, additional reporting requirements may apply. Each distributor should determine whether a state report is required, and should comply accordingly.

It is recommended that the same person conduct the investigation, decide (perhaps in consultation with one or more superiors) whether or not to cancel the order, and also provide the report to DEA.

c. Documentation

All additional contact with DEA, either by telephone or in person, should be documented; and a record of the contact should be maintained.

VI. EMPLOYEES, TRAINING AND STANDARD OPERATING PROCEDURES

a. Employees/Training

Individuals working in CS areas should be screened and selected for their attention to detail, ability to recognize the importance of accuracy, length of tenure with the company and work ethic.

It is recommended that employee training:

- Include a review of DEA rules and regulations;
- Fully cover the firm's procedures for compliance;
- Include backup training to cover instances when the employee primarily responsible for monitoring for suspicious orders will not be available (e.g., due to vacation leave or sick leave); and
- Provide for periodic retraining.

It is recommended that training be conducted for all personnel involved in:

- Receiving, shipping, handling and record-keeping with respect to CS items;
- Sales, or in establishing new accounts and persons who interact with customers; and
- Reviewing, investigating and/or deciding whether to fill orders.

All such training should be documented, and the documentation should be maintained.

b. SOPs

It is recommended that, to implement these Industry Compliance Guidelines, specific written company SOPs be developed and maintained.

VII. ADDITIONAL RECOMMENDATIONS

It is recommended that a distributor include in its "system" provisions for:

- Periodic internal audits of suspicious orders, compliance procedures and results;
- Periodic reviews and revisions of internal SOPs for compliance with §§ 1301.71(a) and 1301.74(b) and new DEA guidance, as well as employee training requirements/procedures;
- Periodic review of the distributor's system for monitoring for suspicious orders, including the system design and the thresholds, to determine whether revisions should

be developed. For example, if the FDA approves a new controlled substance, or a new indication for use of an existing controlled substance, or if DEA makes new information available regarding a Drug of Concern, revisions to the thresholds may be needed; and

- If appropriate, update customer and/or order records on the basis of information obtained while investigating an order under Section IV above.

Glossary of Abbreviations

	Abbreviation	Explanation of Term
	ARCOS	Automation of Reports and Consolidated Orders System
	C.F.R.	Code of Federal Regulations
	C-I, C-II, C-III, C-IV, C-V	References the DEA's designation of individual controlled substances into one of the five levels under 21 C.F.R. § 1308
	CS	Controlled Substances has the meaning given in section 802(6) of Title 21, United States Code (U.S.C.)
	CSA	Controlled Substances Act
	DEA	Drug Enforcement Administration
	DOJ	Department of Justice
	FDA	Food and Drug Administration
	HDMA	Healthcare Distribution Management Association
	NABP	National Association of Boards of Pharmacy
	NDC	National Drug Code
	NTIS	National Technical Information System
	SKU	Stock Keeping Unit
	VIPPS	Verified Internet Pharmacy Practice Sites